**STATE OF MISSOURI**
**MISSOURI BOARD OF PHARMACY**

IN RE:

OMNICARE PHARMACY OF THE MIDWEST, LLC
d/b/a/ OMNICARE OF KANSAS CITY
10400 Hickman Mills Dr., Suite 200
Kansas City, MO 64137

Complaint No. 2018-007249

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND OMNICARE PHARMACY OF THE MIDWEST, LLC d/b/a OMNICARE OF KANSAS CITY**

COME NOW OMNICARE PHARMACY OF THE MIDWEST, LLC d/b/a Omnicare of Kansas City ("Respondent" or the "Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate as a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("AHC") and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witness appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its

permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For purposes of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true, stipulates with the Board that Respondent's license as a pharmacy, numbered 2006009026, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

## JOINT STIPULATION OF FACTS

1. The Missouri Board of Pharmacy is an agency of the State of Missouri created and established pursuant to §338.110, RSMo (2016),[1] for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Omnicare Pharmacy of the Midwest, LLC d/b/a Omnicare of Kansas City, 10400 Hickman Mills Dr., Suite 200, Kansas City, MO 64137 is permitted by the Board under license number 2006009026. Respondent's license was at all times relevant herein current and active.

3. On December 4, 2018, a Board investigator conducted a routine inspection of Omnicare of Kansas City, a long-term care pharmacy (Class A, C, H, J).

4. The investigator discovered 151 outdated drug products in the pharmacy active inventory. These products were set aside and photographed by the investigator. A summary list is included as Exhibit A.

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[1] All statutory references are the to the Revised Statutes of Missouri (2016) unless otherwise noted.

5. The investigator also issued a compliance notice for failure to have electronic recordkeeping system policies and procedures.

6. The investigator also issued a compliance notice for a drug stored with inadequate closure based on finding a Nystatin Cream stored on the pharmacy shelf in active inventory opened, punctured, and not sealed with a closure, lid, or cap.

7. The investigator also issued a compliance notice for failure to wipe down materials prior to placement in the primary engineering control.

8. The investigator also noted the following violations:

A. Pharmacists have expired pharmacist licenses posted;

B. Pharmacy shelves contained excessive dust;

C. Return to stock bubble packs have stickers placed such that the prescription number is no longer visible;

D. Pharmacy is assigning repackaged drug products expiration dates greater than 12 months;

E. Multiple repackaged products assigned MM/YY expiration dates resulting in the possibility of greater than 12 month dating;

F. Repackaged drug product labeled only with drug name/strength and not with lot number and expiration date;

G. Improper repackaging/reuse of drugs by punching out returned bubble packaged cards and repacking into different bubble card;

H. Four IV bags of Vncomycin 1.25mg found stored in the refrigerator without individual labels with name/strength of drug and beyond-use date;

I. Areas of rust found in buffer room, including the filter/vent on the ceiling, the metal shelving with numerous areas of rust and chips, the metal cart with numerous areas of rust and chips, the vent in the lower area of the wall of the buffer room, and on the edge of two metal areas of the pass-through doors;

J. Vent located in the buffer room on lower area of the wall contains unidentified dark yellow crusty substance caked on each vent slat;

K. Back screen of both the primary engineering control (PEC) in the buffer room is being cleaned only with isopropyl alcohol and not with a germicidal agent followed by isopropyl alcohol as required.

9. The compliance notices issued for failure to have electronic recordkeeping system policies and procedures and for failure to wipe down materials prior to placement in the primary engineering control were second compliance notice violations.

10. On March 9, 2020, the Board's investigator conducted a follow-up inspection to the December 3, 2019 inspection. Many of the same violations were noted in the follow up inspection including:

A. Areas of rust on PEC;

B. Vent located in buffer room with rust;

C. Rust and buildup on the metal strip in each corner where doors open from the ante room to the buffer room and on the side doorway;

11. In addition, the follow-up inspection found that the vent located in the buffer room has a slat which contains a shedding material and identified a chip in the metal next to the floor in the back corner area to the right of the PEC.

12. Despite the violations identified in December 2019, the facility continued to prepare sterile compounds. During February 2020, they had 520 sterile compounds, which included frozen and pre-mixed IV's.

13. In December 2020, Respondent provided a response stating that repairs would be completed by March 2021, agreeing to perform monthly spot checks, and to review cleaning procedures.

## JOINT CONCLUSIONS OF LAW

14. Cause exists to take disciplinary action against Respondent's pharmacy permit under 20 CSR § 2220-2.010(6), which provides:

> (6) Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are for employee personal use or that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances. Areas used for this type of drug storage must be clearly identified. Any prescription drugs that are present in a licensed pharmacy but are for the personal use of pharmacy personnel must be labeled in accordance with section 338.059, RSMo.

15. Cause also exists to take disciplinary action against Respondent's pharmacy permit under 20 C.S.R. § 2220-2.010(1)(F), which provides:

> (F) All pharmacies shall be maintained in a clean and sanitary condition at all times.

16. Cause also exists to take disciplinary action against Respondent's pharmacy permit under 20 C.S.R. § 2220-2.200(7)(A), which provides:

> (A) Controlled areas must be clean and well-lit and shall be free of insects, rodents, and/or other vermin. Trash shall be disposed of in a timely and sanitary manner and at least daily. Tacky mats or similar articles are

prohibited in the controlled area or any ISO classified environment.

17. Cause also exists to take disciplinary action against Respondent's pharmacy permit under 20 C.S.R. § 2220-2.200(17)(E), which provides:

> (E) Primary engineering controls shall be cleaned with a germicidal cleaning agent followed by sterile alcohol.

18. Cause also exists to take disciplinary action against Respondent's pharmacy permit under § 338.055.2(5), (6), (13) and (15), RSMo, which provides:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
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> (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
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> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
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> * * *
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> (13) Violation of any professional trust or confidence;
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> * * *
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> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

## JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

1. Respondent's pharmacy license numbered 2006009026 shall be placed on PROBATION for a period of FIVE YEARS ("disciplinary period"). The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

A. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

B. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If requested, Respondent shall provide the Board a list of names and license numbers of all licensed pharmacists employed by Respondent.

D. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

E. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

F. Respondent shall not serve as an intern training facility for interns.

G. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

H. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

I. Respondent shall select an independent pharmacist consultant for the purpose of reviewing and ensuring the pharmacy's compliance with all applicable laws and regulations related to sterile compounding. The consultant shall be a Missouri licensed pharmacist whose license is current and not subject to disciplinary action by the Board. The consultant shall have expertise in sterile pharmacy compounding and shall not be an employee of the Respondent. Within thirty (30) days of the beginning of probation, Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval. Within thirty (30) days of the beginning of probation, the said consultant shall visit the pharmacy, evaluate and provide corrective actions to remedy the issues outlined in this agreement/order, conduct a review of the Respondent's sterile compounding activity for compliance with all applicable laws and regulations, and submit a written report to the Board office within thirty (30) days of the visit. The consultant's report shall include the suggested corrective actions, a timeline for the pharmacy to complete such corrective actions, items/areas reviewed for compliance with applicable laws and regulations during the visit, any deficiencies noted, and a plan to correct any deficiencies noted. The consultant shall then conduct similar visits and provide ongoing reports to the Board office every three (3) months during the first two (2) years of the discipline period, and then on a six (6) month cycle thereafter. All consultant reports are due at the Board office within thirty (30) days of the consultant's visit to the pharmacy. The consultant shall be hired at Respondent's expense.

J. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

2. Prior to the expiration of the disciplinary period, Respondent may petition the Board to shorten the length of the probation. If Respondent petitions the Board to shorten the probation, the Board will consider the petition, but the Board makes no representations or promises regarding the response to any such petition by Respondent.

3. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

4. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

5. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C.

§1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

**RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,**

**_____ REQUESTS**

**__✓__ DOES NOT REQUEST**

**THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE AS A PHARMACY.**

Respondent understands that it may, either at the time the Settlement Agreement is signed by all parties, or within fifteen (15) days thereafter, submit the Settlement Agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Respondent's permit. If Respondent desires the Administrative Hearing Commission to review this Agreement, it may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65101.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

OMNICARE PHARMACY OF THE MIDWEST, LLC d/b/a OMNICARE OF KANSAS CITY

By: _____

Print Name: Leo Lariviere Dir Regulatory Affairs

Date: 01/11/22

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____
Kimberly Grinston
Executive Director

Date: 1-28-2022

TGH LITIGATION LLC

By: _____
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*Attorneys for Missouri Board of Pharmacy*